北京大学科研伦理与科研诚信培训第十六期（模块 **B**）日程

2017 年 12 月 5 日（星期二），时间：下午 01:00 - 04:30

地点：北京大学医学部逸夫教学楼 502

12:40 - 01:00	签到	
01:00 - 02:00	美国伦理委员会面临的问题与挑战：杜克大学的经验	David Matesanz
02:00 - 03:00	研究者的依从性要求	June Walker
03:00 - 03:10	休息	
03:10 - 03:40	科研诚信	丛亚丽
03:40 - 04:30	问题与讨论	

Current Issues Facing U.S. IRBs

A Focus on the Regulations

Duke University Health System
Institutional Review Board

DukeHealth

Agenda

- Background on Regulations
  - Highlights of changes to Common Rule and NIH Requirements
  - Single IRB Requirements
- Case Studies on Review Procedures at Duke
  - Ensuring Expertise on Review Boards
  - Distinction Between Care and Research
  - Communications Within HRPP

Duke University – Durham, North Carolina

Duke University Medical Center

Facts and Figures

- Duke University Health System and Medical Center have approximately 28,000 full-time employees.
- Duke University School of Medicine and School of Nursing have over 1500 faculty members.
- The Duke Clinical Research Institute, the world's largest academic research organization, has more than 1,200 faculty and staff.
- Duke Health has an annual research budget in excess of $650 million FY16

Background on Duke Health IRB

- 9 Convened Boards
- 8,000+ Active Protocols
- 15 IRB Chairs, 16 Staff Members

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
New Protocol Applications	1598	1642	1634	1685	1749	1888	2005
Continuing Reviews	3485	3727	3918	3992	4032	4233	4519
Amendments & Personnel Changes	9737	12544	14296	15864	16604	18646	21006

The Regulations that Govern Us

Office for Human Research Protections

45 CFR 46 (The Common Rule)
OHRP Guidance

Food and Drug Administration

21 CFR 50/56
21 CFR 312 (for IND studies)
21 CFR 812 (for IDE studies)

Office for Civil Rights

45 CFR 160/162/164 (HIPAA)

Duke Policies

NC State Law

Federal Requirements for IRB Approval

In addition to the various regulations governing the composition and function of an IRB, specific criteria must be documented as having been satisfied before the IRB can issue approval. These criteria are described in 45 CFR 46.111 and the corresponding FDA regulations in 21 CFR 50.111.

The specific criteria can be found in the Primary Reviewer Checklists on the Duke IRB website.

Constant Changes

- 21st Century Cures Act
- Revised Common Rule
- New NIH Terms (Single IRB, Certificate of Confidentiality)
- Electronic Consent

Conflicting Regulations

- HIPAA and Common Rule
- Common Rule and FDA

Major Changes to the Common Rule

1. New definition of human subject
2. Changes to informed consent
3. Added waiver requirement
4. Changes continuing review requirements
5. Changes exemption categories
6. Concept of broad consent
7. Single IRB requirement

Change in Definitions

- Human Subject
  - Means a living individual about whom an investigator (whether professional or student) conducting research:
    - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- Reasonable person standard

Elements of IRB Review

Consent Document (old rule)

Provide the following information to the potential participant:

- Purpose of the study and funding source
- Complete description of study activities
- Duration of participation in study
- Potential risks, anticipated benefits
- Costs and compensation
- Voluntary nature of participation and right to withdraw

Elements of IRB Review

Consent Document (old rule) (cont'd)

Provide the following information to the potential participant:

- Alternatives to study participation
- Treatment for study-related injury
- Who will see study data, how it will be managed, when it will be de-identified or destroyed
- Whom to contact with questions, concerns, or study-related injuries

Consent Forms – New Common Rule

- What changes?
  - Concise summary
  - Statement that identifiers might be removed and data/specimens used for future research
- If applicable:
  - Whether whole genome sequencing will occur (if known)
  - Statement that specimens may be used for commercial profit
  - Whether clinically relevant results will be conveyed to subjects

Overseeing Without Continuing Review

- The new Common Rule no longer allows for routine continuing review for studies that are minimal risk.
  - Continuing review is a mechanism that IRBs use to identify potential concerns through annual updates from study teams
  - How does the IRB/HRPP continue to monitor minimal risk studies?
  - How are study teams educated?

Broad Consent

The revised Common Rule establishes a new broad consent alternative for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. The rule specifies requirements for the consent process, consent elements, and documentation of consent, and establishes that consent may not be waived when individuals are asked to provide broad consent and refuse.

- How is it used?
- How long does a “no” last and how broadly does it apply?
- How is it tracked?

U.S. Single IRB Requirements

- National Institutes of Health
  - NIH Policy on the Use of a Single IRB for Multi-Site Research sets expectation of a single IRB
  - Goes into effect January 2018
- Common Rule
  - Any U.S. institution engaged in cooperative research must rely upon approval of a single IRB
  - January 2020

Pros and Cons of Single IRB Review

- Pros
  - One point of review
  - Faster process
  - More consistent study design
- Cons
  - A big cultural shift
  - Loss of local control
  - Unclear division of responsibilities
  - Retooling of IRB offices

Experiences from Duke

Case: Preventing Deferrals

Case Example:

- At many institutions deferrals are common
- Can present lengthy delays to research
  - Delays are costly
  - Delays prevent people from participating

Goal: Limit deferrals

Case: Preventing Deferrals

- How do we meet our goal?
  - We cannot approve research that does not meet ethical criteria
- Solution: Pre-meeting review
  - IRB staff conduct first review
  - Meeting Chairs and Primary Reviewers
  - Identify issues prior to meeting
  - Work with study team to have solutions in place
  - Allows for modifications instead of deferral

Case: Preventing Expirations

- Expiring protocols were previously a frequent occurrence at Duke
  - Difficult to know whether all research activities have ceased
  - Presents problems with funding agencies
- Goal: Zero expirations
- Achieved by shift in culture. Support at high levels.

Ensuring Expertise

- How can you be sure that the composition of a board is sufficient to review the research?
- How broadly do you define expertise in a particular area?
- Do you assign protocols to reviewers with expertise?

Ensuring Expertise

The 9 Duke Health IRBs are comprised of representatives from:

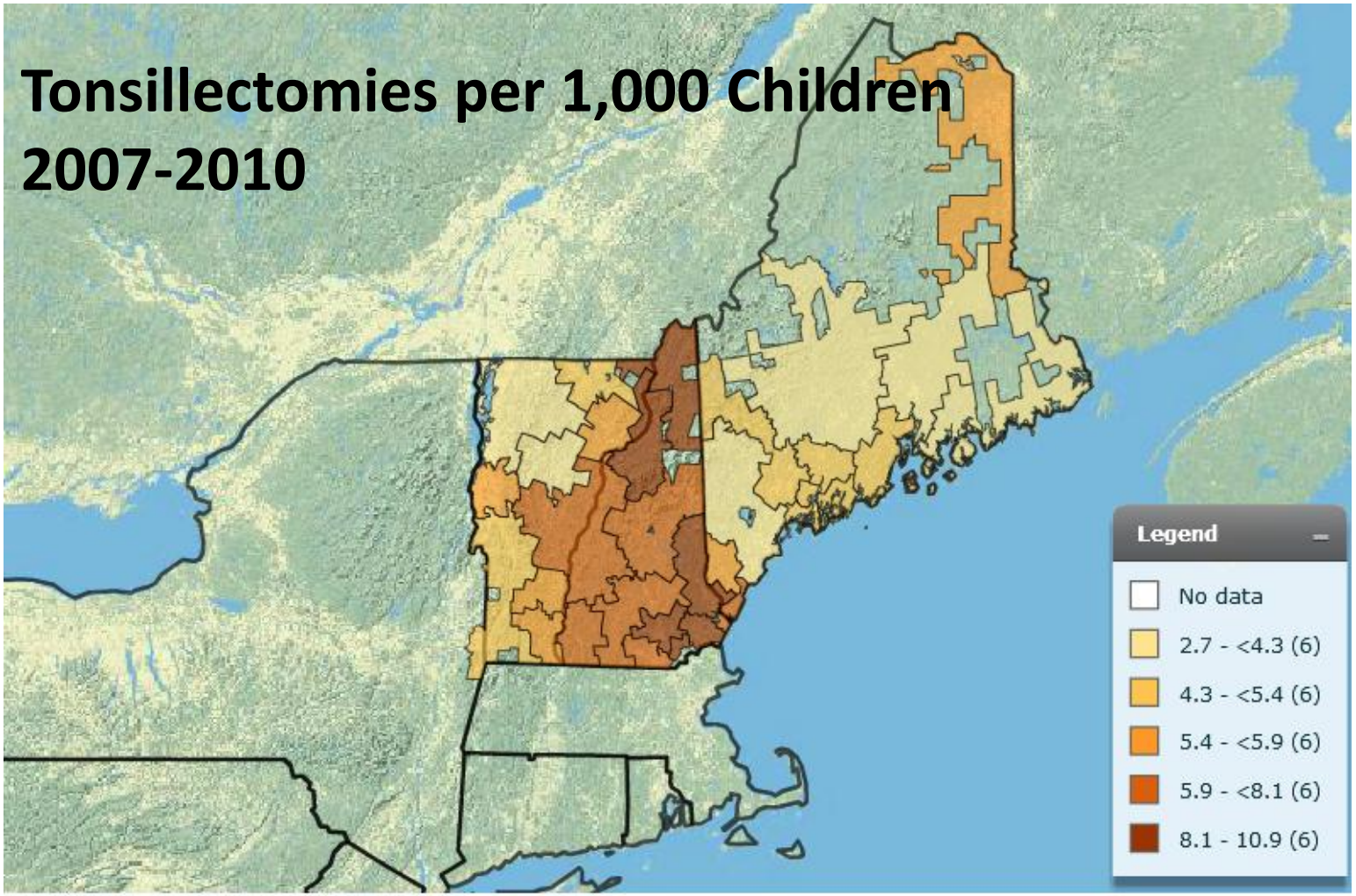
Anesthesiology
Cancer Center
Dept. of Medicine
Nursing Administration
Obstetrics & Gynecology
Pediatrics
Pharmacy
Psychiatry
Surgery
Community & Family Medicine
Duke Clinical Research Unit (DCRU)
Nursing School
Ophthalmology
Pathology
Radiation Oncology
Radiology
Medical School Students
Duke University Departments

and the surrounding Triangle community. There are currently about 200 IRB members serving on the DUHS IRB.

Evaluating Care vs Research

- How does the IRB make the distinction between care and research?
- How can you be certain that there you have enough information?
  - Due diligence?
  - Detailed description of procedures vs. standard of care?
- Equipoise

Standard of Care Varies



www.dartmouthatlas.org

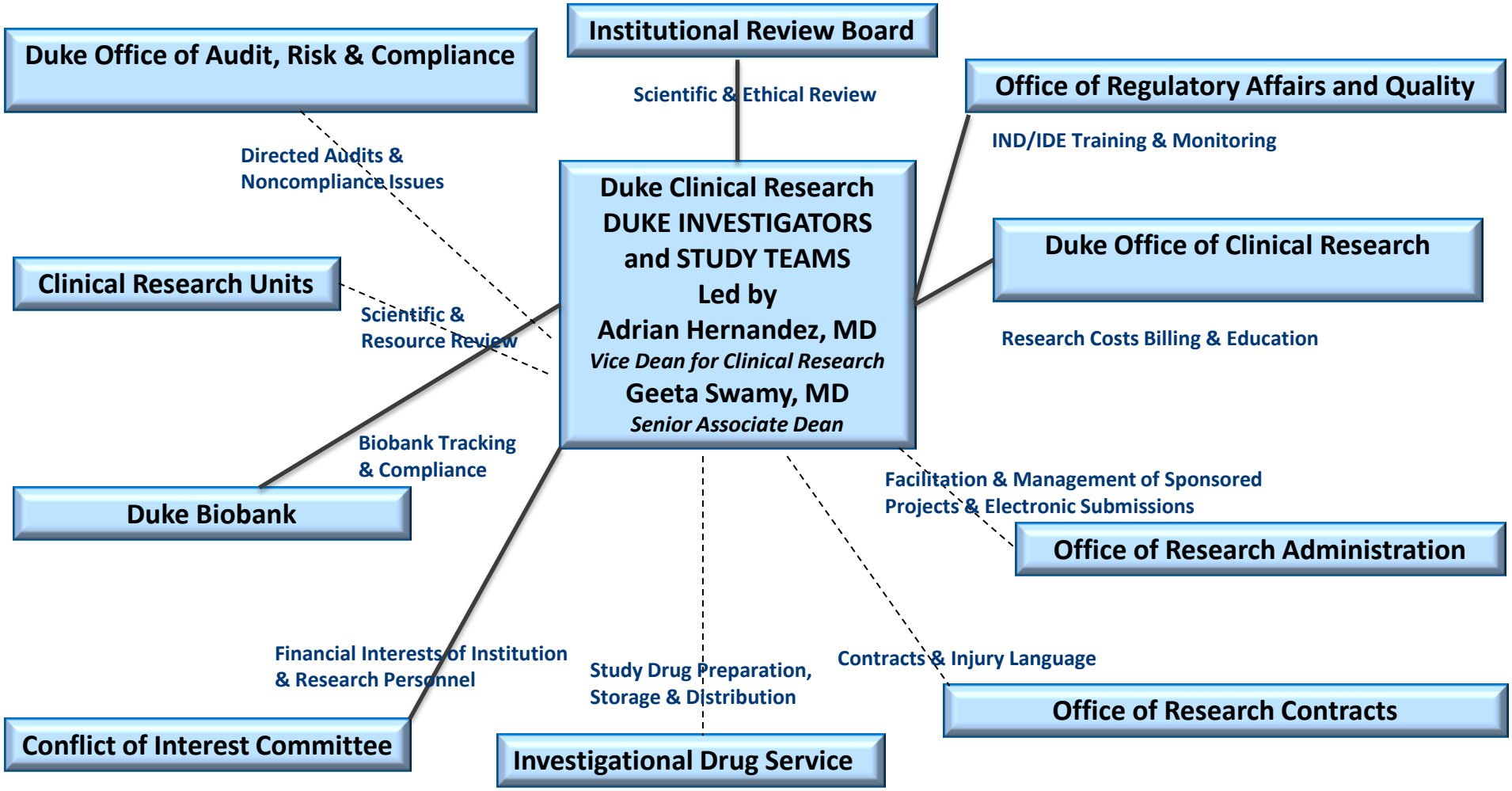
Communication Among HRPP

- How do you ensure that a large, complex HRPP communicates among itself?
- How do new Single IRB requirements impact communication?

- Establish clear “swim lanes”
- Implement a liaison system

- Tone from the Top

Communication: Duke Health HRPP



Case Study: Data Transfer

- Data leaving the institution had few checks and balances
- Researchers attested that they had IRB approval and a data transfer agreement was initiated
- Review found that researchers often misinterpreted their IRB approval or did not know the correct terms

Case: Data Transfer

Solution

1. Training
2. Implement a system of communication between the IRB and Office of Research Contracts
   - Pre-approve all requests for data transfer
   - Compare against IRB approved protocol
   - Require changes if inconsistent

Meaningful Informed Consent

- Constant tension between sponsor consent forms and what is meaningful for a research participant
  - Consent forms have consistently grown
  - How can we promote a more meaningful consent process?
  - More information is not always better
  - Common Rule changes

- New Technologies
  - E-consent

Meaningful Informed Consent

- How can the IRB facilitate meaningful informed consent?
  - Tools and training
  - Staff editors
  - Requiring detailed consent plans
  - Promoting resources and providing guidance

Most Common Trouble Spots After IRB Approval

- Inappropriate recruitment/consent
  - disregard for subject privacy
  - coercion (primary care physician as PI)
- Inadequate record keeping by the study team
- Inadequate reporting of safety events to IRB, sponsor, FDA
- Inappropriate handling or inventory of drugs/devices/biologics
- Inadequate oversight by the PI

Questions and Discussion

David Matesanz, JD
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Investigator Responsibilities for IRB Compliance

The Duke Perspective

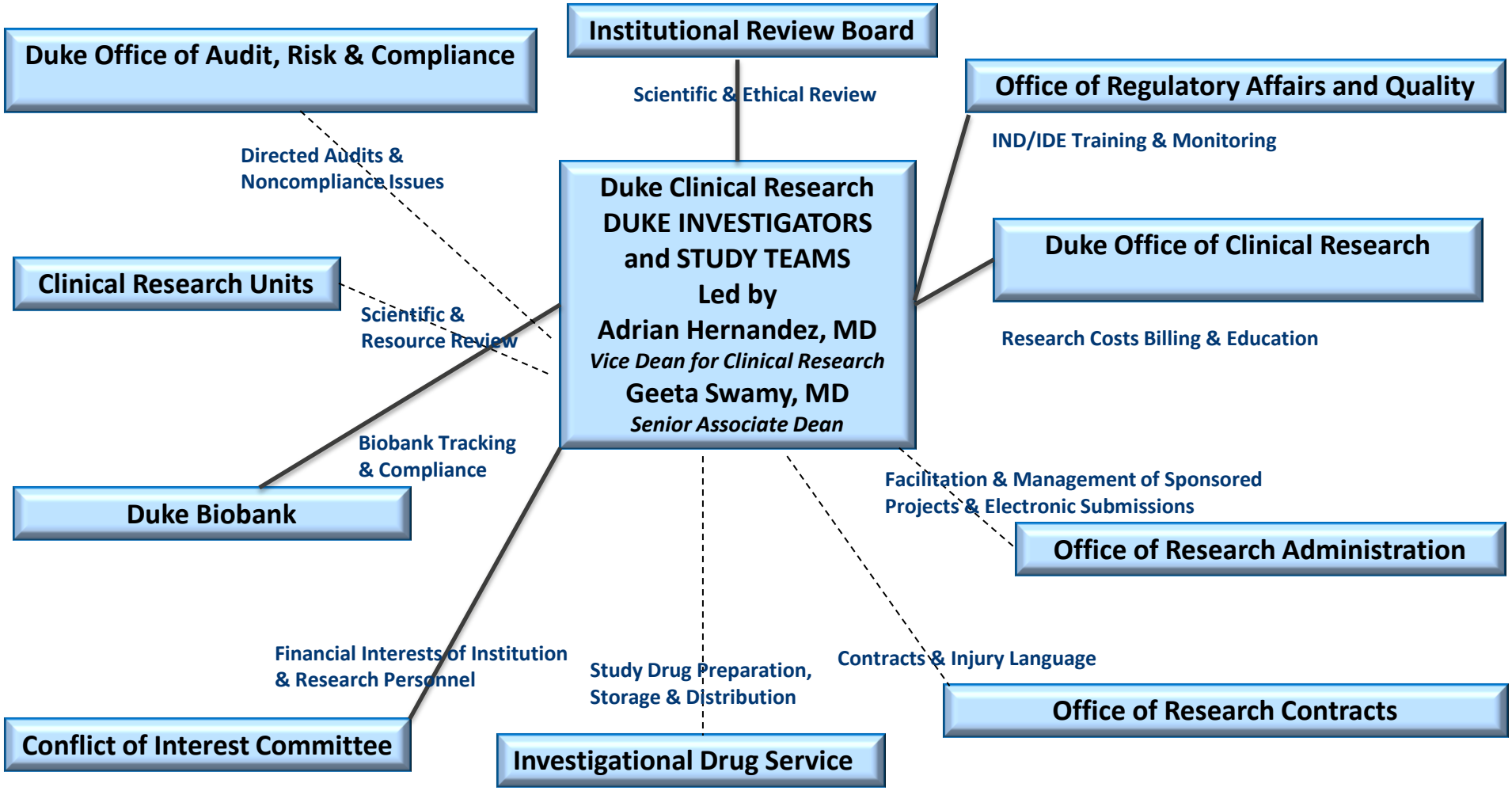
DukeHealth

Institutional Review Board

Presentation Outline

I. The Duke Health HRPP and the Role of Investigators
II. Ethical and Regulatory Training of Investigators
III. Duke Investigator Responsibilities
IV. Noncompliance Process – Failure to Follow the Rules

Duke Health Human Research Protection Program (HRPP) 2017



According to Duke's Federal Wide Assurance

An institution holding an OHRP-approved Federal Wide Assurance (FWA) is responsible for ensuring that its investigators conducting HHS-conducted or -supported human subjects research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects.

The Regulations that Govern Us

Office for Human Research Protections (OHRP)

45 CFR 46 (The Common Rule)
OHRP Guidance

Food and Drug Administration

21 CFR 50/56
21 CFR 312 (for IND studies)
21 CFR 812 (for IDE studies)

Office for Civil Rights

45 CFR 160/162/164 (HIPAA)

DUHS Policies

North Carolina State Law

Investigator Training

- OHRP strongly recommends that institutions and their designated IRBs establish training and oversight mechanisms (appropriate to the nature and volume of their research) to ensure that investigators maintain continuing knowledge of, and comply with, the following:
  - relevant ethical principles;
  - relevant federal regulations;
  - written IRB procedures;
  - OHRP guidance;
  - other applicable guidance;
  - state and local laws; and
  - institutional policies for the protection of human subjects.

Duke Investigator Responsibilities

- Investigator ethical and regulatory training requirement
  - All Duke Health researchers must complete the required training before they are placed on a protocol submitted to the Duke Health IRB, and before they can gain access to eIRB.
  - 17 CITI modules

Duke's Process for Providing Education for Investigators

Requirements

- 17 CITI modules to be completed online, then a "refresher" every 3 years by all study team members

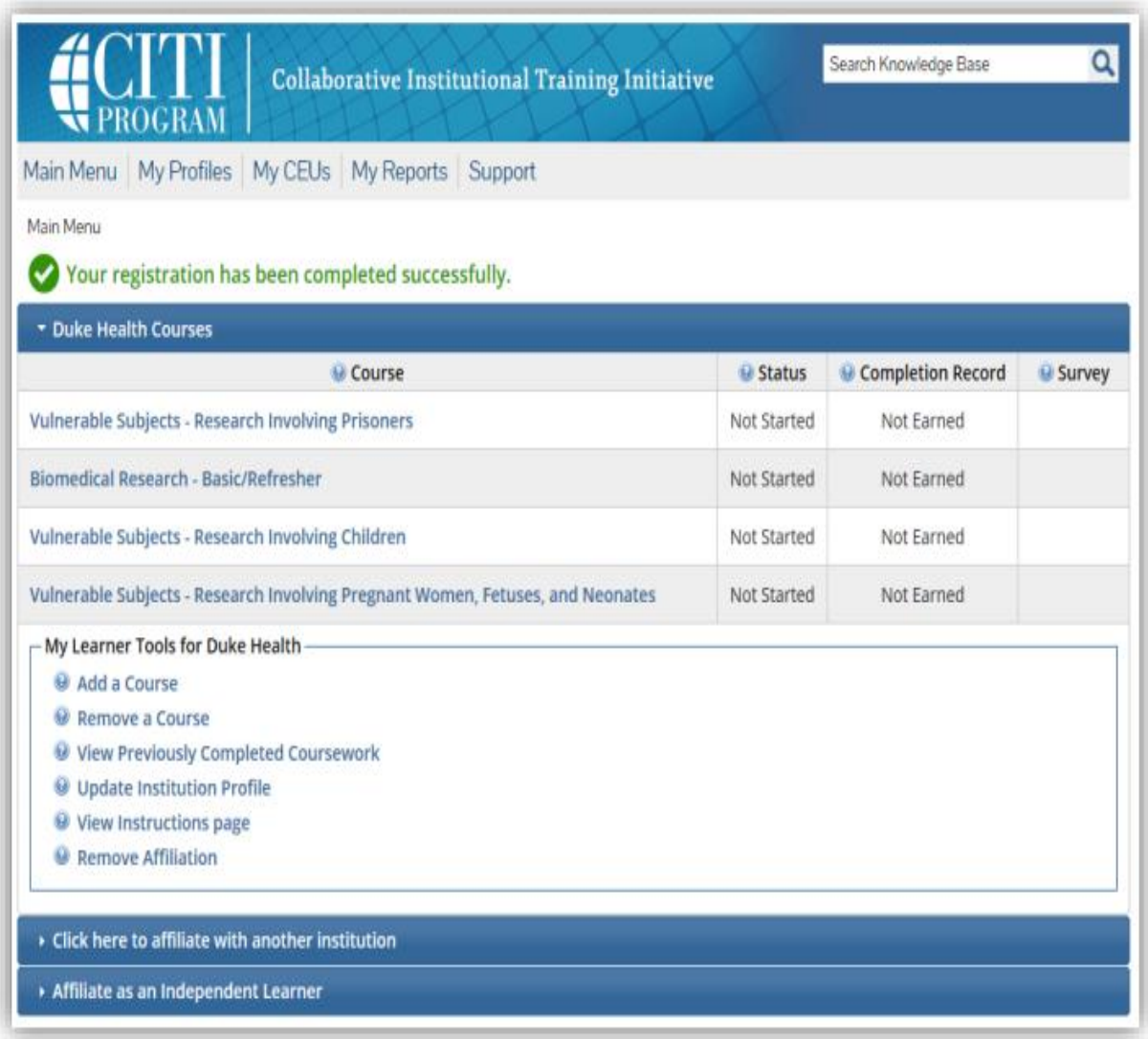
Penalties

- IRB approval letter is not issued until all study team members have completed training and either provided written documentation to the IRB or the training can be confirmed through online records

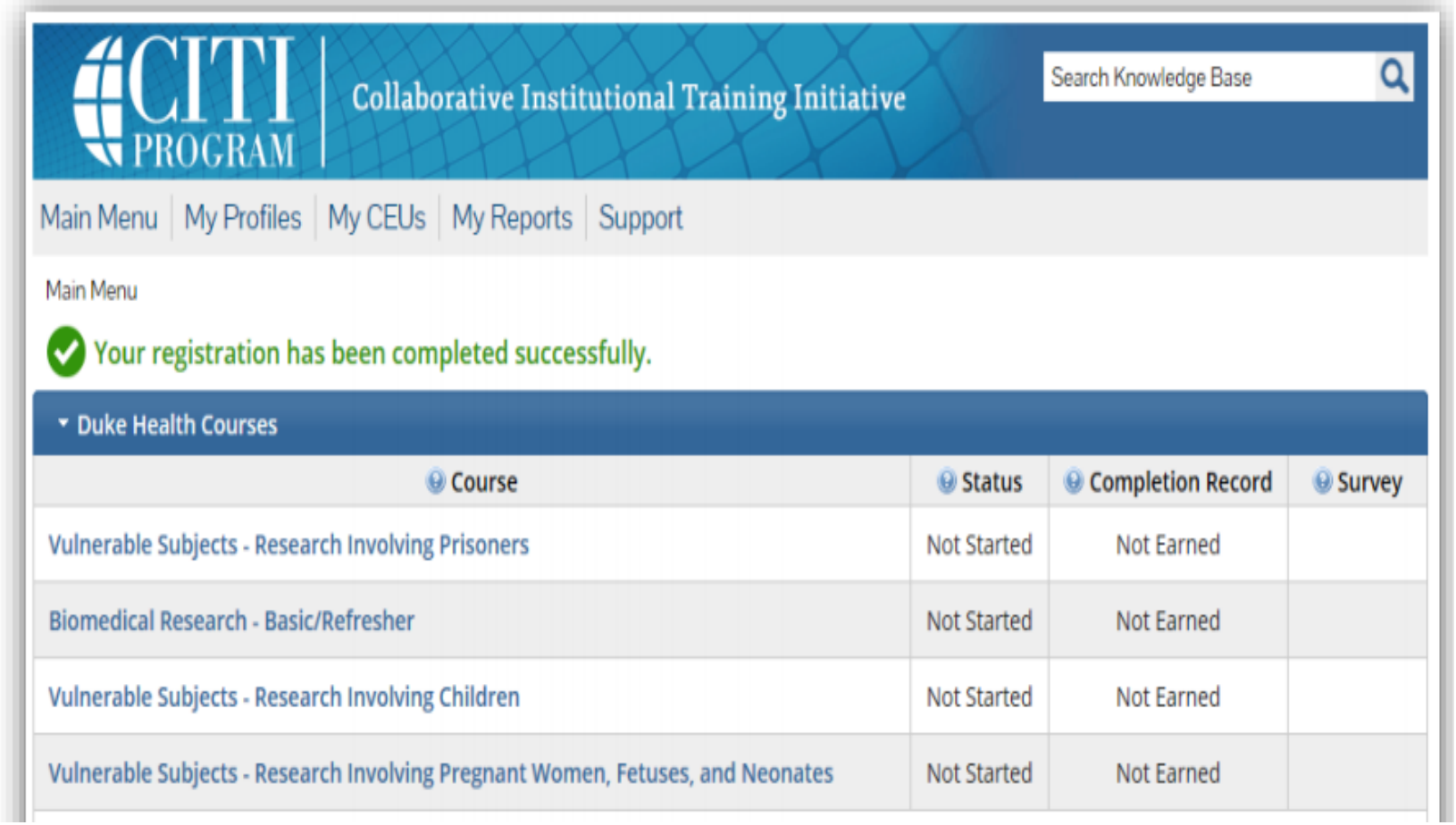
Monitoring

- IRB office staff check training for all study team members with each annual submission (new study or continuing review)

CITI Requirements



CITI Requirements



CITI Module List

Module ID:	Module:
1363	Audits and Inspections of Clinical Trials
1364	Completing the CITI GCP Course
1355	Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
1360	Detecting and Evaluating Adverse Events
1354	ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations
1359	Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
1356	Investigator Obligations in FDA-Regulated Research
1357	Managing Investigational Agents According to GCP Requirements
1362	Monitoring of Clinical Trials by Industry Sponsors
1352	Overview of ICH GCP
1351	Overview of New Drug Development
1358	Overview of U.S. FDA Regulations for Medical Devices
1361	Reporting Serious Adverse Events
9	Research Involving Children
10	Research Involving Pregnant Women, Fetuses, and Neonates
8	Research Involving Prisoners
1350	The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices

Duke Health Principal Investigator Agreement

DUHS PRINCIPAL INVESTIGATOR AGREEMENT

Commitment of a Duke University Health System Principal Investigator or Co-Principal Investigator to Institutional Human Subject Protection Policies and IRB Oversight Under Federal-Wide Assurance, FWA# 00009025

Name of DUHS Investigator: _____

Department/CRU Affiliation: _____

If you are a Principal Investigator or a Co-Principal Investigator, please read and sign the agreement below.

I intend to participate in research for which initial and continuing review will be provided by the Duke University Health System (DUHS) Institutional Review Board (IRB), or by another IRB that the DUHS IRB has agreed upon. I understand that one of the conditions of my participation in such research is my acceptance of my responsibilities under this Agreement to comply with institutional policies, applicable federal, state, and local laws and regulations, ethical guidelines, and other policies and principles as described below.

(1) I am familiar with, and will comply with, applicable federal regulations and guidance for the protection of human subjects: HHS regulations at 45 CFR 46 and associated guidance; FDA regulations at 21 CFR

Duke Investigator Responsibilities

- I am familiar with, and will comply with, applicable federal regulations and guidance for the protection of human subjects: HHS regulations at 45 CFR 46 and associated guidance; FDA regulations at 21 CFR Parts 50, 54, 56, 312, 314, 601, 812, and 814 and associated guidance; the HIPAA privacy regulations at 45 CFR Parts 160 and 164 and associated guidance; the DUHS Federal-Wide Assurance; and relevant institutional policies and procedures for the protection of human research subjects.

Duke Investigator Responsibilities

- I recognize the authority of the DUHS IRB to oversee human subject research, as described in the Federal-Wide Assurance, and I will abide by all decisions of the IRB.

- I will assume overall administrative responsibilities for all aspects of each research study approved under this Agreement. I will conduct the research according to the IRB-approved protocol, maintain appropriate oversight of the research study and supervision of my research staff, and appropriately delegate research responsibilities.

Duke Investigator Responsibilities

- I will ensure that all members of my research staff, and all others directly involved in the conduct of the study, are qualified by education, training, and experience to perform their research responsibilities. I will inform my staff of any pertinent changes during the course of a study, and arrange for education or additional training of staff as needed.

Duke Investigator Responsibilities

- If I arrange with a source outside of DUHS to provide information critical to the study, I will take steps to ensure that the outside source can verify the integrity of data and records provided to me.

Duke Investigator Responsibilities

- I will employ sound research design in accordance with the standards of my discipline.

- I will recruit subjects in a fair and equitable manner, weighing the potential benefits of the research to the subjects against their vulnerability and the risks to them.

Duke Investigator Responsibilities

- If the research involves more than minimal risk to research subjects, I will provide the IRB with an adequate data and safety monitoring plan for promptly detecting harm and mitigating potential injuries.

Duke Investigator Responsibilities

- I will have determined, before initiating a research study, that the necessary resources are present to conduct the study, including access to a sufficient number of potential subjects, adequate time to conduct the research, an adequate number of qualified staff, adequate facilities, and the availability of needed medical and psychological resources that subjects may require as a consequence of research participation.

Duke Investigator Responsibilities

- I will comply with the IRB's prompt reporting requirements:
  - Serious adverse events
  - Unanticipated problems involving risk to subjects or others (UPIRTSO)
  - Protocol deviations & violations
  - Noncompliance
  - Study-related deaths

From OHRP Guidance: Recommended Reporting Timelines

OHRP recommends the following guidelines in order to satisfy the requirement for *prompt reporting:*

- **Unanticipated problems that are serious adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event.**

- **Any other unanticipated problem should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.**

Duke's Reporting Requirements

- **Unanticipated study-related death: 24 hours**
- **Reportable Serious Adverse Event: 1 week**
- **Protocol Deviation/Violation: 2 weeks**
- **These timelines and the noncompliance policies are posted on the Duke IRB web site.**

Duke Investigator Responsibilities

- I will seek, document, and maintain records of informed consent and HIPAA authorization from each research subject or the subject's legally authorized representative as required under applicable regulations and requirements of the IRB. I will develop an informed consent process emphasizing the importance of subject comprehension and voluntary participation.

Duke Investigator Responsibilities

- I will ensure that the informed consent process is led only by individuals who have appropriate training and knowledge of the research, including any investigational product involved, in order to discuss the risks and benefits of the study with prospective subjects. Only appropriate staff listed as “Key Personnel” in my IRB submission will be authorized by me to conduct the consent process with prospective subjects.

Duke Investigator Responsibilities

- I agree to cooperate with the IRB as it conducts initial and continuing review, including providing required information, records, reports, and certifications. I will ensure that the periodic continuing review of my research will occur within the time frame stipulated by the IRB, and no research will continue beyond the designated approval period.

Duke Investigator Responsibilities

- If I conduct research involving an FDA-regulated product under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application, I will comply with all applicable FDA regulations and fulfill all investigator responsibilities [or investigator-sponsor responsibilities, where appropriate], including those described on Form FDA 1572, and at 21 CFR 312 and 812.
- And I will be familiar with the information in the Investigator's Brochure, including the potential risks and side effects of the investigational product.

Duke Investigator Responsibilities

- I will not enroll subjects in research prior to receiving final approval of the research by the IRB. I will report promptly to the IRB proposed changes in the research. I will not initiate changes in research activities without prior review and approval by the IRB, except when necessary to eliminate immediate hazards to the research subjects.

Duke Investigator Responsibilities

- I understand that emergency medical care may be delivered to a research subject without IRB review and approval to the extent permitted under applicable Federal regulations and State law. I will provide, or arrange to provide, a reasonable standard of medical care to study subjects for medical problems arising during their participation in the research.

Duke Investigator Responsibilities

- My research staff and I will respond in a timely manner to any subject's complaints, suggestions or requests for information. If I am unable to resolve a complaint satisfactorily, then I will report the complaint to the IRB. In addition, I will respond promptly to IRB queries regarding a subject complaint.

Duke Investigator Responsibilities

- I will generally be available (by phone or other electronic communication) to subjects during the study. If I will be unavailable during the study, I will delegate study responsibility to a specific qualified person who will be available in my absence. I will inform the IRB of this delegation of authority, via a protocol amendment, as a change in the research activity requiring IRB review.

  -includes such extended periods of time for personal leave, maternity/paternity leave, or sabbatical

Duke Investigator Responsibilities

- If I am unable to meet my responsibilities as principal investigator (PI) or co-principal investigator (Co-PI), I will inform the IRB of the change and seek IRB approval for a new PI or Co-PI to continue the study, or request closure of the study.

Duke Investigator Responsibilities

- I will cooperate with any inquiry by the Duke University Compliance Program, including audits, concerning any research with humans in which I participate. In the event that institutional officials determine that I have failed to comply with this Agreement, I agree to take recommended action(s), including, but not limited to, termination of my participation in designated research activities.

Duke Investigator Responsibilities

- In the event I am found to have failed to comply with any of these requirements and, as a result, the convened IRB has made a recommendation of serious and/or continuing noncompliance with the DUHS Institutional Official's subsequent concurrence, the IRB will report the event(s) to institutional officials, the Office for Human Research Protections (OHRP), and/or the FDA, as appropriate.

Duke Investigator Responsibilities

- I acknowledge that my primary responsibility as a principal investigator or co-principal investigator is to safeguard the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Duke Investigator Responsibilities

- All Duke investigators will report annually to the Research Integrity Office Conflict of Interest (COI) Committee and disclose any financial conflicts per institutional reporting rules.
- If a COI management plan is issued, the investigator will abide by the requirements of the management plan.

What is Noncompliance?

- **Noncompliance is the failure to follow the IRB-approved protocol and related study documents, applicable laws and regulations, and institutional and IRB policies.**

- **Noncompliance can occur on the part of the Investigators, the research subject, IRB, or any other institutional department associated with the HRPP.**

Degrees of Noncompliance

Serious Noncompliance

Noncompliance that creates an increase in risks to subjects, adversely affects the rights, welfare and safety of the research subjects or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious noncompliance.

Continuing Noncompliance

A pattern of noncompliance that if allowed to continue is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study.

Examples of Noncompliance

On the part of the study team:

- **enrollment of ineligible subject**
- **omission of study test that could affect subject safety or data analysis**
- **not reporting serious adverse events to IRB**

On the part of the IRB:

- **failure to document findings in meeting minutes**
- **failure to externally report UPIRTSOs (Unanticipated Problems Involving Risk to Subjects or Others) to federal agencies**

What is a UPIRTSO?

- **Unanticipated Problem Involving Risk to Subjects or Others**

1. Unexpected

   - in terms of nature, severity, or frequency

2. New Risk

   - indicates that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

Examples

UPIRTSO

- Chemotherapy dosing errors
- Medical device fails and gives incorrect readings
- Stolen laptop containing identifiable study data

Serious or Continuing Noncompliance

- Study team member fabricates study visit
- Study team member personally accepts incentives from sponsor

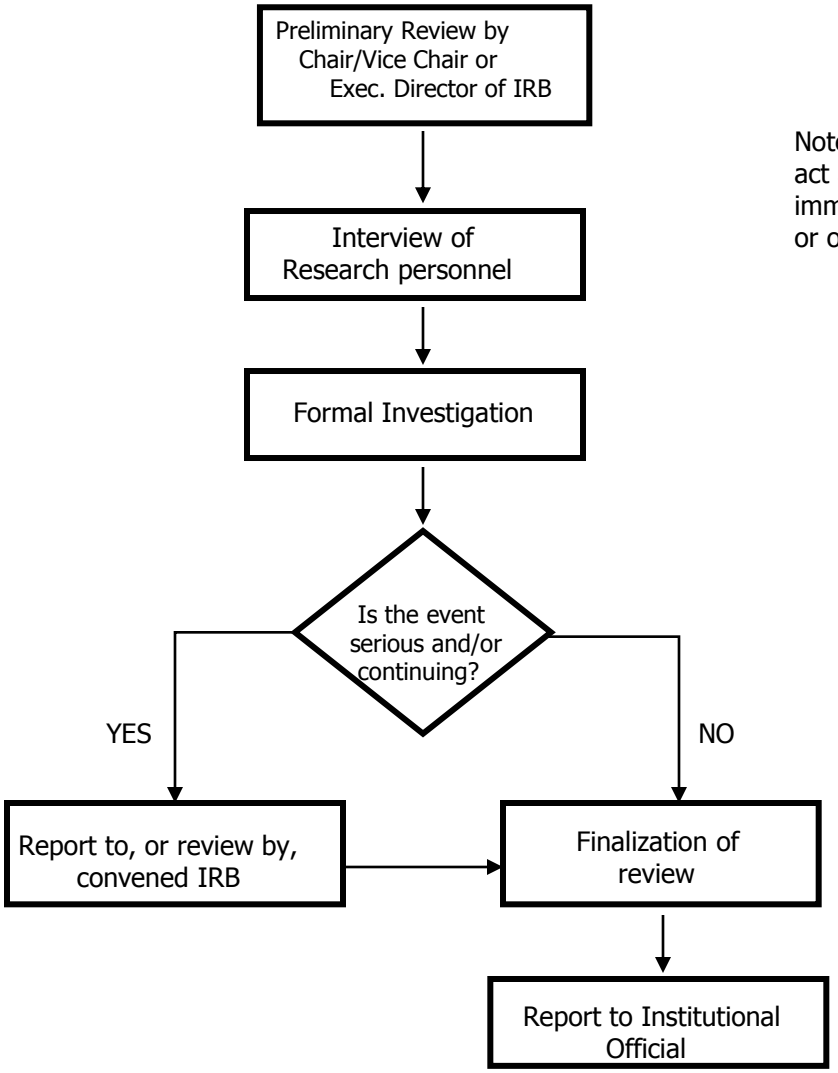
The Process at Duke

1. Allegations are received by Exec. Director, IRB
   - subject complaints
   - study team or colleague allegations
   - random audit findings

2. Exec. Director completes initial evaluation:
   - resolves with study team/subject
   - contacts study team for explanation
   - calls a committee of experts to evaluate
   - requests a directed audit from Compliance Office, SOM

3. Convened Board review
   - additional corrective actions and determinations
   - reports to Institutional Official, research administration, and external agencies

DUHS IRB Review of Noncompliance



Note: A Chair/Vice Chair can act at any point to eliminate immediate hazard to subjects or others.

Decisions for the IRB

- Does the event constitute an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO)?
- Does the event constitute noncompliance?
- Is the noncompliance serious or continuing?
- Are the proposed corrective actions adequate?
- Do the subjects need to be informed of the event?
- Note: UPIRTSO and serious/continuing noncompliance determinations regarding U.S. federally-funded studies require external reporting to OHRP and federal funding agencies.

Tools for Investigators

To aid Investigators, the institution and IRB must provide:

- **Clear definitions of noncompliance and consequences**
- **Mechanisms for reporting noncompliance**
- **Mechanisms for protecting individuals who bring forth allegations of noncompliance**
- **A culture that encourages self-reporting without imposing severe punitive actions**

In Summary

- **Investigators have responsibility to conduct research ethically and in a manner compliant with applicable regulations and policies.**

- **Partnership between Investigators and the IRB creates a stronger Human Research Protection Program (HRPP).**

Strength Through Cooperation

Contact Information

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https://irb.duhs.duke.edu/

Research Misconduct—Individual and Environment

Yali Cong

Peking University Health Science Center

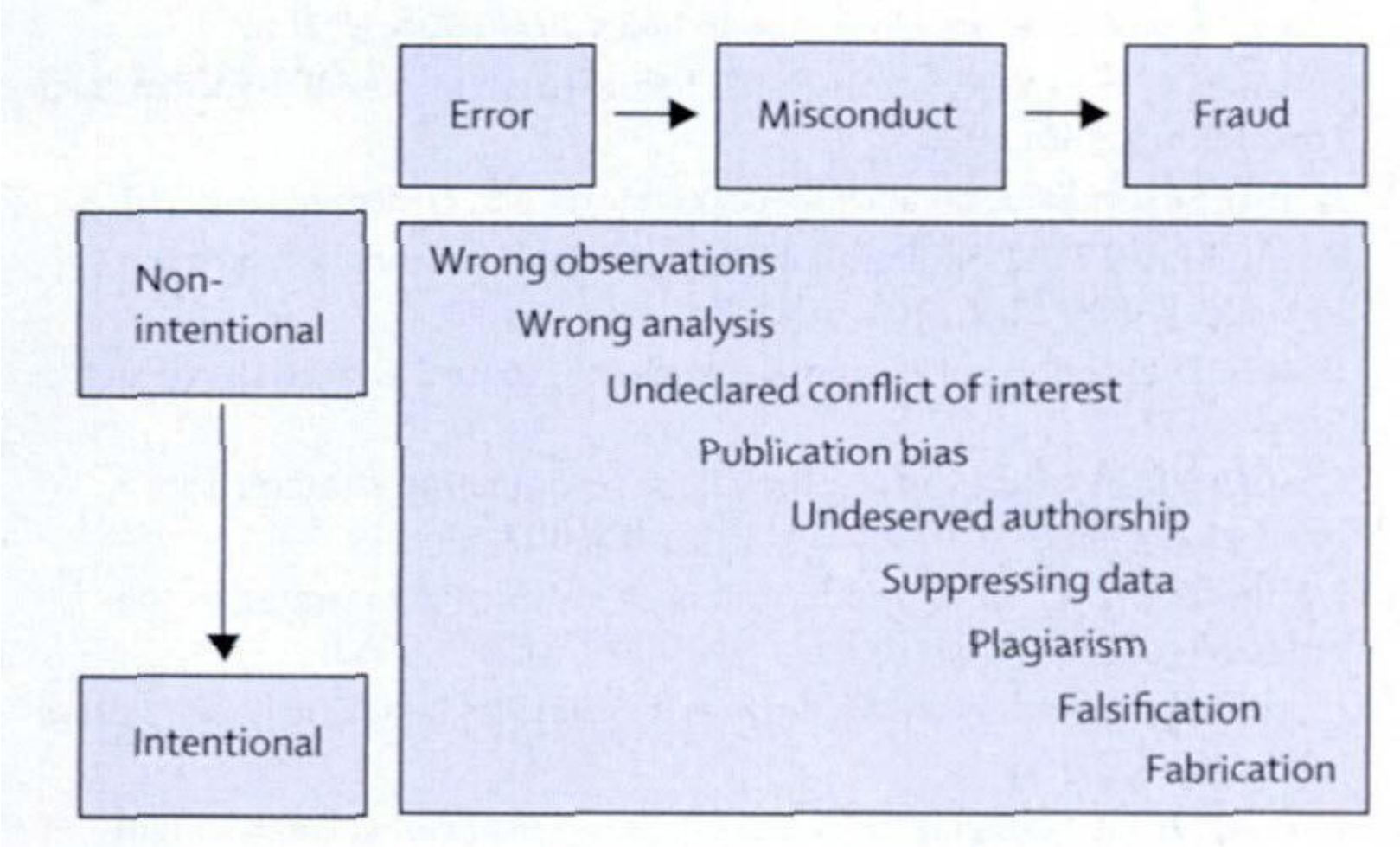
要 点

- 很多的案例
- 共性的问题
- 机构与环境
- 每人的角色
- 大背景和框架
- 厚道的北医

科研不端FFP： **Fabrication ——伪造、Falsification——篡改 、Plagiarism ——剽窃**

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- 不包括诚实的错误和学术观点的不同

Slippery slope between honest errors and intentional fraud



Magne Nylenna; Sigmound Simonsen. ***The Lancet; 2006, 367, 9526, pg 1882***

上海交大汉芯事件(2006)

从项目的评审——项目的中期评估——项目的终结

低端的造假，评审专家责任在那儿？

当时对当事人的惩处：没有制定；只是MOE撤销其长江学者，大学开除其职务

Scientific fraud: action needed in China

On Dec 19, 2009, editors at *Acta Crystallographica Section E* alerted the scientific community to a disgraceful pattern of fraud involving papers they had published in 2007. At least 70 false crystal structures were reported—mainly from two groups led by Hua Zhong and Tao Liu, both at Jinggangshan University, Jian, China. All authors have now agreed to retraction of 41 papers published by Zhong and 29 by Liu. It is rather surprising that wrongdoing on such a scale evaded detection during peer review and, considering that crystal structures are deposited in public databases upon publication, that the truth has been uncovered so slowly.

In China, the government controls almost all funding for research. As in other countries, to gain funding researchers need to publish as many papers in high impact journals as possible. According to *Science Citation Index* and other resources, Chinese authors published 271 000 papers in 2008, roughly 11·5% of the world's total. This incident is not the first time that scientific fraud has occurred in China. Regulations to monitor state-funded research projects were 2006 by the Ministry of Science

in response to six high-profile cases of scientific misconduct. A new circular was issued on March 19, 2009, aimed at preventing misconduct in higher education institutions—punishment for breaching the new rules could involve warnings, dismissal, or legal action. Research programmes could be suspended or terminated, funding could be withdrawn, or awards and honours revoked.

Such extensive fraud is disappointing—not only does it indicate a substantial waste of research time and money, but it is likely that, whatever punishments do result, damage to the reputations of the researchers, institutions, and journal concerned is likely to be disproportionately great. Clearly, China's Government needs to take this episode as a cue to reinvigorate standards for teaching research ethics and for the conduct of research itself, as well as establishing robust and transparent procedures for handling allegations of scientific misconduct to prevent further instances of fraud.

For Hu Jintao's goal of China becoming a research

中国生命科学研究，不断出现的对剽窃、篡改数据和伪造简历等行为的指控

《自然·医学》2006年8月 Vol 12, 8：867

Frequent cases force China to face up to scientific fraud

re.com/naturemedicine

Six high-profile cases of scientific misconduct over eight months: for China's biomedical research, still struggling for global credibility, the frequent accusations of plagiarism, falsified data and fabricated resumes spell out a serious warning—one that the government is finally preparing to heed.

Chinese universities have traditionally failed to investigate or even acknowledge cases of misconduct. But in early March, Beijing-based Tsinghua University fired Hui Liu, a professor of medicine, after he

Photo by Guang Niu/Getty Images

Pressure cooker: Fierce competition for funds may be contributing to a rise in cases of scientific misconduct.

grants may have led some scientists to fabricate research, he says. "Previously, the funding and the level of competition in the field were much lower."

China's investment in life sciences has grown as much as 400% in the past five years to RMB13 billion (US$1.6 billion).

China's large pool of patients and cheap skilled biotech researchers have been highly attractive for collaborators outside China, but the recent incidents have struck a note of caution for Chinese scientists abroad.

"We have heard some rumors before,

几个典型案例

- Peking University: Wang Mingming (2002)
- Shanghai Jiaotong University--Hanxin case (2006)
- Tsinghua University: Liu Hui case (2006)
- Jinggangshan University: Zhong Hua and Liu Tao (2009)
- Zhejiang University: He Haibo and Academician Li(2009)
- PUHSC: sue case of authorship between former student and mentor (2009)
- Golden rice: research ethics and(2012)
- 中国科研诚信网 “http://www.sinori.cn/”
- 2015年3月，Biomed Central.41/43;8yue ,springer, 64/64;2015,10月，E类似比尔， 9/9；
- 2017年2月，将于近期陆续撤销在《Tumor Biology》106/106


www.most.gov.cn/kjbgz/201707/t20170727_134289.htm
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学术期刊集中撤稿事件调查处理情况新闻通气会在京召开
日期：2017年07月27日 来源：科技部
2017年7月27日下午，《肿瘤生物学》集中撤稿调查处理情况新闻通气会在科技部召开。科技部政策法规与监督司司长贺德方、教育部科技司副司长李楠、卫生计生委科技教育司监察专员刘登峰、自然科学基金会诚信办主任朱蔚彤、中国科协调研宣传部副部长王挺出席会议。科技部政策法规与监督司司长贺德方代表联合工作组，向各新闻媒体记者通报了《肿瘤生物学》集中撤稿事件彻查处理总体情况和下一阶段工作安排。科技部办公厅主任马连芳主持了通气会。
人民日报、新华社、光明日报、经济日报、中央人民广播电台、中央电视台、科技日报等十余家媒体参加了通气会。
党中央、国务院高度重视科技创新发展，大力营造求真务实、诚实守信的社会氛围和鼓励创造、追求卓越

贺德方介绍，这107篇论文的事实情况总体已经核查清楚。经核查，107篇论文中，有2篇论文系《肿瘤生物学》重复发表；1篇系《肿瘤生物学》期刊自身错误撤稿，作者没有过错，《肿瘤生物学》已公开澄清；10篇存在提供虚假同行评议专家或虚假同行评议意见的问题，其中95篇由第三方机构提供虚假同行评议专家或虚假同行评议意见，6篇由作者自行提供虚假同行评议专家或虚假同行评议意见。这101篇论文中，有12篇系向第三方机构购买；其余的89篇由作者完成，经学术评议认定，其中的9篇存在内容造假，其他80篇系作者完成内容未造假。这107篇论文共涉及作者521人，其中11人无过错，486人不同程度存在过错（这486人中，102为主要责任人，70人为次要责任人，314人没有参与造假），其他尚待查实的24人将按程序先纳入科研诚信"察名单"。各涉事作者所在单位正在按照统一的处理规则，区分涉事作者参与论文造假的事实情况和具体情节依据法律法规等相关规定，对涉事作者进行处理。

贺德方还介绍了已完成事实材料和处理意见与各责任人“两见面”程序、形成明确处理意见的76篇论文的有关情况。这76篇论文涉及376人，各涉事作者所在单位已经提出了具体的处理意见，正在抓紧履行相关程序，对各责任人作出取消一定期限承担科技计划（专项、基金等）项目、晋升职务职称等资格，追回所承担的科技计划（专项、基金等）项目经费，撤销获得的科技奖励、学术奖励、荣誉称号等处理决定。此外，还将根据《中国共产党纪律处分条例》、《事业单位人事管理条例》、《事业单位工作人员处分暂行规定》等有关规定和单位内部规章制度，对相关责任人给予党纪、政纪和其他相应处理。有关具体处理情况将在本单位网站予以公布。对其他被撤稿论文的涉事作者，所在单位也要抓紧完成处理意见与责任人见面程序，尽快作出处理决定。

同时，依据有关单位对撤稿论文的调查情况，科技部已暂停了21名涉事作者参加的20个国家科技计划项目（课题）的立项程序，待责任确定后，对无过错作者的项目将恢复立项程序。自然科学基金会对将撤稿论文作为研究工作基础列入2017年度科学基金申请书中的51个项目采取了终止项目评审的措施。工程院暂停了1名涉事作者的院士候选人资格。

自然基金委十年处罚学术不端者318人次

- 9月20日举行的第十三届中国科协年会科学道德建设论坛
- 国家自然科学基金委纪检监察审计监督局副局长陈越
- 过去10年间（2011-9-21）共有318人次因学术不端而受到国家自然科学基金委处罚。
- 从1999年到2010年，国家自然科学基金委员会共受理投诉举报1380件，其中292件立案调查，占投诉举报的两成。其中属于学术不端的案件有204件，占立案调查的73%，占投诉举报的15%。204件学术不端的案件中，实名举报53件，占26%，匿名举报151件，占74%。
- 318人次中，终止撤销项目的有100人次，69人次受到书面批评，58人次受到内部通报批评，19人次受到国家自然基金委“最严重的处罚”——通报批评，也就是网上公布。
- 此外，先后有15个基金项目依托单位受到了书面批评、内部通报批评或通报批评。

http://news.sciencenet.cn/htmlnews/2011/9/252852.shtm

国家自然科学基金委员会通报科研不端行为典型案例及近期查处的科研不端行为案件处理决定

日期 2016-12-12　　来源：　　作者：　　【大 中 小】　　【打印】　　【关闭】

12月12日上午，国家自然科学基金委员会在北京召开2016年“捍卫科学道德反对科研不端”通报会，对外通报2015-2016年期间查处的8个科研不端行为典型案例，并公布近期查处的61份科研不端行为案件处理决定。

附件：2015-2016年查处的科研不端行为案件处理决定

2015-2016年查处的科研不端行为案件处理决定

关于印晓星、汤道权的处理决定

国科金监决定〔2015〕35号

国家自然科学基金委员会监督委员会收到举报，反映江苏某大学印晓星、汤道权等人的下列4篇论文涉嫌造假：

2015 年 8 月，德国施普林格出版集团（Springer）宣布因伪造同行评审撤销旗下 10 家学术期刊已经发表的 64 篇论文，这些论文全部出自中国作者，在国际上产生极其恶劣的影响，其中包括福建某医院侯建明作为第一兼通讯作者与他人等发表的论文：Jian-ming Hou*, Man Wu, Qing-ming Lin, Fan Lin, Ying Xue, Xu-hua Lan, En-yu Chen, Mei-li Wang, Hai-yan Yang, Feng-xiong Wang. Lactoferrin promote primary rat osteoblast proliferation and differentiation via up-regulation of insulin-like growth factor-1 expression. Molecular Biology Reports, 2014, 41: 5019-5030（标注科学基金项目批准号 81270968）。

经调查核实，该论文第一兼通讯作者侯建明在发表论文过程中委托“第三方”代为投稿，论文审稿人信息和同行评审意见虚假；该论文标注了侯建明主持的科学基金项目（批准号 81270968），并作为工作基础列入侯建明 2014 年度和 2015 年度 2 项科学基金项目申请书（受理号分别为 U140520029 和 8157041751）。

环境、制度因素

- 现在科研基金不是不多，而是不均衡；
- 评审机制需要更透明和更公平；
- 资源分配不合理，导致恶性竞争。胜败论英雄仍然存在——只看结果，不看手段（预设谁都不择手段）；
- 监督和惩罚标准缺乏，力度太弱，铤而走险；
- 缺乏对年轻科学家鼓励和倾斜；
- 财务制度：有钱开会买物，没有钱过日子（2016年之前）；
- ……

机构和个人

- 全国范围内，我国的科研不端，我国较少发生药物研发相关的高端领域，只因缺乏这样的研究而已；
- 政府层面，很关注，出于长期的科研发展，也部分出于政治压力和颜面；
- 机构层面，有的还主要看重对自己机构的利益，基金额度，忽略或牺牲的是社会公平和正义，以及社会对科研的信任；表现为，帮助研究者获得资源，而忽略监督研究者科研过程的合规性；
- 个人层面，不仅研究者群体没有引起关注，还有一个潜在的研究者群体——学生，只是完成“作业”的心理，走捷径的心理，没有把此当做科研和关涉自身名誉的事情；
- 面对曝光的镜头，各种学术不端者总是怀揣各种理由，其中最常见的是把责任推脱给不合理的考评制度和科研体制，而没有反观自身；
- ……

我们对待whistleblower的文化

中国科研诚信网
Promoting Research Integrity
科学技术部科研诚信建设办公室主办

管理部门 | 科研人员 | 高校师生 | 科教机构 | 学术团体 | 出版单位 | 站内搜索 搜索

首页 -- 文章正文

举报须知

作者： 中国科研诚信网 时间： 2009-10-10 来源： 中国科研诚信网 2112 次阅读

科学技术部

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为了维护科

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一般来说，有关部门对属于下列情况的举报不予受理：

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3. 没有具体的违法事实，或者举报事项难以查证的。

对于科学基金和科学技术计划管理、科学技术奖励和中国科学院、中国工程院院士增选工作中的异议，应按有关部门的规定执行。

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每个人、机构的角色

- 中庸：「射有似乎君子，失诸正鹄，反求诸其身。」
- 《心经》第一句：观自在菩萨
- 我国药业研发，已看到不断出现的不端行为事件——高起点跻身国际话语圈
- 机构，应出台相关政策

Dishonesty：everyone

我校曾经的政策，正在调整——不惟SCI——现在的情况？

- 2000年北京大学医学部，修订了《北京大学医学部博士研究生在学期间发表论文的规定》，至少2篇在国际或国内期刊发表或被接受，其中1篇应发表在SCI影响因子≥0.5以上。若≥2，1篇即可。后来，包括985，211在内的知名高校，都类似规定。
- 一调查显示，58.2%学生对此压力较大或非常大，只有31.2%认为可以讲压力转化为动力
- 中国科学技术信息研究所发表的信息现实，我国（除港澳台）在世界发表科技论文的份额8.3%,排世界第二；高校在2009和2010，均占82%左右。
- 科研诚信教育主战场，在高校和研究所

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谢 谢 ！